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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 1 of 13 Attorney Docket Number KAP 100 CIP

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	3,993,073	Zaffaroni		11-23-1976		
	4,167,179	Kirsch		09-11-1979		
	4,351,337	Sidman		09-28-1982		
	4,427,005	Tener		01-24-1984		
	4,697,575	Horowitz		10-06-1987		
	4,700,692	Baumgartner		10-20-1987		
	4,706,652	Horowitz		11-17-1987		
	4,754,745	Horowitz		07-05-1988		
	4,763,642	Horowitz		08-16-1988		
	4,815,449	Horowitz		03-28-1989		
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	5,059,156	Fischell, et al.		10-22-1991		
	5,242,373	Scott, et al.		09-07-1993		
	5,342,283	Good		08-30-1994		

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>
		Office,*	Number <sup>4</sup>	Kind Code <sup>2</sup> (if known)				
	PCT	WO 95/03036			angiogenesis Technologies	02-02-1995		
	PCT	WO 96/14880			PGK Corporation	05-23-1996		
	PCT	WO 97/19706			IBT Technology Partners	06-05-1997		
	PCT	WO 00/32238			Scimed Life Systems, Inc.	06-08-2000		
	PCT	WO 00/41185			Nycomed Amersham PLC	07-13-2000		
	PCT	WO 00/43045			Photogen, Inc.	07-27-2000		

Examiner Signature	Date Considered
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 2 of 13

**Complete if Known**

Application Number 10/665,793

Filing Date September 19, 2003

First Named Inventor Edward J. Kaplan

Group Art Unit

Examiner Name

Attorney Docket Number KAP 100 CIP

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		5,424,288	Order	06-13-1995	
		5,460,592	Langton, et al.	10-24-1995	
		5,486,360	Ballagh, et al.	01-23-1996	
		5,536,726	Order	07-23-1996	
		5,595,979	Snyder	01-21-1997	
		5,620,700	Berggren	04-15-1997	
		5,626,629	Koutrouvelis	05-06-1997	
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		5,650,442	Mitchell, et al.	07-22-1997	
		5,871,437	All	02-16-1998	
		5,888,026	Hunter, et al.	03-23-1998	
		6,159,143	Lennox	12-12-2000	
		6,241,982	Nicolini, et al.	06-05-2001	
		6,248,057	Mavlyt, et al.	06-19-2001	
		6,391,279	Singh et al.	05-21-2002	

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		Office <sup>2</sup>	Number <sup>2</sup>	Kind Code <sup>2</sup> (if known)			
		PCT	WO 00/51639	Halogenetics, Inc.	09-08-2000		
		PCT	WO 00/57923	North American Scientific	10-05-2000		
		PCT	WO 01/36007	Angiotech Pharmaceuticals	05-25-2001		
		PCT	WO 02/30472	Guildford Pharmaceuticals	04-18-2002		

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## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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Sheet 3 of 13 Attorney Docket Number KAP 100 CIP

**Complete If Known**

Application Number 10865 793

Filing Date September 19, 2003

First Named Inventor Edward J. Kaplan

#### **Group Art Unit**

#### **Group A Unit**

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#### **Executive Name**

Attorney Docket Number: KAB 100-CIR

U.S. PATENT DOCUMENTS

#### FOREIGN PATENT DOCUMENTS

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## Complete If Known

Application Number 10/665,793

Filing Date September 19, 2003

First Named Inventor Edward J. Kaplan

Group Art Unit

Examiner Name

Attorney Docket Number KAP 100 CIP

Sheet 4 of 13

## OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No.*	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>+</sup>
		ALONSO, et al., "Biodegradable microspheres as controlled-release tetanus toxoid delivery systems," <i>Vaccine</i> 12: 299 (1994).	
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		BEER, et al., "Extended release of adenovirus from polymer microspheres: potential use in gene therapy for brain tumors," <i>Adv. Drug Deliv. Rev.</i> 27: 59 (1997).	
		BENZINA, et al., "Studies on a new radiopaque polymeric biomaterial," <i>Biomaterials</i> 15: 1122 (1994).	
		BREM, et al., "Biodegradable polymers for controlled delivery of chemotherapy with and without radiation therapy in the monkey brain," <i>J. Neurosurg.</i> 80: 283 (1994).	
		BREM, et al., "Interstitial chemotherapy with drug polymer implants for the treatment of recurrent gliomas," <i>J. Neurosurg.</i> 74: 441 (1991).	
		BREM, et al., "Placebo-controlled trial of safety and efficacy of intraoperative controlled delivery by biodegradable polymers of chemotherapy for recurrent gliomas," <i>Lancet</i> 348: 1008 (1995).	
		BOBOCHAK, et al., "A recombinant polymeric hemoglobin with conformational, functional, and physiological characteristics of an <i>in vivo</i> O <sub>2</sub> transporter," <i>Am. J. Physiol. Heart Circ. Physiol.</i> 285: H549-H561 (2003).	
		CAMARATA, et al., "Sustained release of nerve growth factor from biodegradable polymer microspheres," <i>Neurosurg.</i> 30: 313 (1992).	
		CARDINALE, et al., "Effect of interstitial and/or systemic delivery of irapazamine on the radiosensitivity of human glioblastoma multiforme in nude mice," <i>Radiation Oncol. Invest.</i> 6: 63 (1998).	

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Application Number	10/665,793
Filing Date	September 19, 2003
First Named Inventor	Edward J. Kaplan
Group Art Unit	
Examiner's Name	
Attorney Docket Number	KAP 100 CIP

Sheet

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of

13

**OTHER ART – NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		CHATTARAJ, et al., "Biodegradable microparticles of influenza viral vaccine: comparison of the effects of routes of administration on the in vivo immune response in mice," <i>J. Control. Rel.</i> 58: 223 (1999).	
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		CONFORTI, et al., "Anti-inflammatory activity of polyphosphazene-based naproxen slow-release systems," <i>J. Pharmacol.</i> 48: 488 (1998).	
		DASH & CUDWORTH II, "Therapeutic applications of implantable drug delivery systems," <i>JPM</i> 40: 1 (1998).	
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		DOMB, et al., "Polyanhydrides I: Preparation of high molecular weight polymers," <i>J. Polym. Sci.</i> 25: 3373 (1967).	
		DURING, et al., "Controlled release of dopamine from a polymeric brain implant: in vivo characterization," <i>Ann. Neurol.</i> 25: 351 (1989).	
		EWEND, et al., "Local delivery of chemotherapy and concurrent external beam radiotherapy prolongs survival in metastatic brain tumor models," <i>Research</i> 56: 5217 (1996).	
		FOWLER, et al., "Evaluation of an implant that delivers leuprolide for one year for the palliative treatment of prostate cancer," <i>Urology</i> 55: 639 (2000).	

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			Application Number	10/665,793	
Sheet	6	of	13	Filing Date	September 19, 2003
				First Named Inventor	Edward J. Kaplan
				Group Art Unit	
				Examiner Name	
				Attorney Docket Number	KAP 100 CIP

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		FUNG, et al., "Pharmacokinetics of interstitial delivery of carbamustine, 4-hydroperoxy cyclophosphamide, and paclitaxel from a biodegradable polymer implant in the monkey brain," <i>Cancer Res.</i> 58: 672 (1998).	
		*GANZA-GONZALEZ, et al., "Chitosan and chondroitin microspheres for oral-administration controlled release of metoclopramide," <i>Eur. J. Pharm. Biopharm.</i> 48: 149-155 (1999).	
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		HARPER, et al., "Enhanced efficacy of a novel controlled release paclitaxel formulation (PACLIMER Delivery System) for local-regional therapy of lung cancer tumor nodules in mice," <i>Clin. Canc. Res.</i> 5: 4242 (1999).	
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		HORAK, et al., "New radiopaque polyHEMA-based hydrogel particles," <i>J. Biomed. Mat. Res.</i> 34: 183 (1997).	
		HORIUCHI, et al., "Radiotherapy for carcinoma of the tongue with special emphasis on advanced cases," <i>J. Jap. Soc. Cancer Ther.</i> 15(5): 851-857 (1980).	

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Sheet	7	of	13	Filing Date	September 19, 2003
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	JAIISWAL, et al., "Long-term multiple color imaging of live cells using quantum dot bioconjugates," <i>Nature Biotechnol.</i> 21: 47-51 (2003).		
	JUDY, et al., "Effectiveness of controlled release of a cyclophosphamide derivative with polymers against rat gliomas," <i>J. Neurosurg.</i> 82: 481 (1995).		
	"KAKIZAKI, et al., "Lipidharmanmicrosphere (LHM). A new type of totally synthetic oxygen carrier and its oxygen carrying ability," <i>Art. Cells Blood Substit. Immobil.</i> 22: 933-936 (1994).		
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	KONG, et al., "Intralesionally implanted cisplatin plus systemic carbamustine for the treatment of brain tumors in rats," <i>J. Surg. Oncol.</i> 69: 78 (1998).		
	KUBEK, et al., "Prolonged seizure suppression by a single implantable polymeric-TRH microdisk preparation," <i>Brain Res.</i> 609: 189 (1998).		
	KUNOU, et al., "Controlled intraocular delivery of ganciclovir with use of biodegradable scleral implant in rabbits," <i>J. Control. Rel.</i> 37: 143 (1995).		
	KURIAKOSE, et al., "Interleukin-12 delivered by biodegradable microspheres promotes the antitumor activity of human peripheral blood lymphocytes in a human head and neck tumor xenograft/scid mouse model," <i>Head &amp; Neck</i> p. 57 (2000).		
	LAURENCE, et al., "Bioerodible poly(ether amide)s for antibiotic drug delivery: in vitro osteomyelitis treatment in a rat model system," <i>J. Orthopaedic Res.</i> 11: 256 (1993).		
	"LEBUGLE, et al., "Study of Implantable calcium phosphate systems for the slow release of methotrexate," <i>Biomaterials</i> 23: 3517-3522 (2002).		

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		LEIBEL & PHILLIPS, <i>Textbook of Radiation Oncology</i> (1998).	
		"LENDLEIN, et al., "Biodegradable, elastic shape-memory polymers for potential biomedical applications," <i>Science</i> 295: 1673-1676 (2002).	
		LESTER, et al., "Assessment of barium impregnated polyethylene spheres (BIPS®) as a measure of solid-phase gastric emptying in normal dogs – comparison to scintigraphy," <i>Vet. Radiol. Ultrasound</i> 40: 465 (1999).	
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		"MERRICK, et al., "Seed fixity in the prostate/priprostatic region following brachytherapy," <i>Int. J. Radiation Oncol. Biol. Phys.</i> 46: 215-220 (2000).	
		"MINAMIMURA, et al., "Tumor regression by inductive hyperthermia combined with hepatic embolization using dextran-magnetite-incorporated microspheres in rats," <i>Int. J. Oncol.</i> 18: 1153-1158 (2000).	
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Application Number	10/665,793				
Filing Date	September 19, 2003				
First Named Inventor	Edward J. Kaplan				
Group Art Unit					
Examiner's Name					
Sheet	9	of	13	Attorney Docket Number	KAP 100 CIP

**OTHER ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		MIYAMOTO, et al., "Biodegradable scleral implant for intravitreal controlled release of fluconazole," <i>Curr. Eye Res.</i> 16: 930 (1997).	
		MORITERA, et al., "Biodegradable microspheres containing adriamycin in the treatment of proliferative vitreoretinopathy," <i>Invest. Ophthalmol. Vis. Sci.</i> 33: 3125 (1992).	
		"MOROZ, et al., "Artificial embolization hyperthermia in porcine renal tissue," <i>J. Surg. Res.</i> 105: 209-214 (2002).	
		PARK, et al., "Biodegradable polyanhydride devices of celazolin sodium, bupivacaine, and tetrox for local drug delivery: preparation and kinetics and mechanism of in vitro release," <i>J. Control. Rel.</i> 52: 179 (1998).	
		PEREZ & BRADY, <i>Principles and Practice of Radiation Oncology</i> , 3 <sup>rd</sup> ed, p. 54 (1998).	
		PERKA, et al., "The use of fibrin beads for tissue engineering and subsequent transplantation," <i>Tiss. Eng.</i> 7: 359-361 (2001).	
		PHILIPPE, et al., "Local and sustained delivery of 5-fluorouracil from biodegradable microspheres for the radiosensitization of glioblastoma," <i>Cancer</i> 88: 325 (1999).	
		POGGI, et al., "Marker and seed migration in prostate localization," <i>Int. J. Radiation Oncol. Biol. Phys.</i> 56: 1248-1251 (2003).	
		PRESTIGE, et al., "Post-treatment biopsy results following permanent transrectal ultrasound-guided interstitial brachytherapy in early stage prostate cancer," <i>Int. J. Radiation Oncol. Biol. Phys.</i> 32(Suppl 1): 144 (1995).	
		QIAN, et al., "Fabrication and characterization of controlled release poly(D,L-lactide-co-glycolide) microspheres," <i>J. Biomed. Mater. Res.</i> 55: 512 (2001).	

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number	10/666,793
Sheet	10	of	13	Filing Date	September 19, 2003
				First Named Inventor	Edward J. Kaplan
				Group Art Unit	
				Examiner Name	
				Attorney Docket Number	KAP 100 CIP

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		RAMIREZ, et al., "Biodegradable poly(DL-leucine-co-glycolic acid) microspheres containing tetracaine hydrochloride. In-vitro release profile," <i>J. Microencapsulation</i> 16: 105 (1999).	
		REINHARD, et al., "Polymeric controlled release of dexamethasone in normal rat brain," <i>J. Control. Rel.</i> 16: 331 (1991).	
		RINGKJOB, "Treatment of intracranial gliomas and metastatic carcinomas by local application of cytostatic agents," <i>Aeta Neurol. Scandav.</i> 44: 316 (1968).	
		ROBERTO, et al., "Structure and dosimetric analysis of biodegradable gels for prostate cancer treatment," <i>Art. Organs</i> 27: 432-433 (2003).	
		SANCHEZ, et al., "In vivo study of the tissue distribution and immunosuppressive response of cyclosporin A-loaded polyester micro- and nanospheres," <i>Drug Deliv.</i> 2: 21 (1995).	
		SCHEIBEL, et al., "Conducting nanowires built by controlled self-assembly of amyloid fibers and selective metal deposition," <i>Proc. Natl. Acad. Sci.</i> 100: 4527-4532 (2003).	
		SEE, et al., "Brachytherapy and continuous infusion 5-fluorouracil for the treatment of locally advanced, lymph node negative, prostate cancer," <i>Cancer</i> 77 (5): 924-927 (1996).	
		SENDEROFF, et al., "Führin based drug delivery systems," <i>J. Parenter. Sci. Technol.</i> 45: 2-6 (1991).	
		SIVAKUMAR, et al., "Preparation, characterization and in vitro release of gentamicin from coralline hydroxyapatite-gelatin composite microspheres," <i>Biomaterials</i> 23: 3175-3181 (2002).	
		STRAW, et al., "Effects of cis-diamminedichloroplatinum II released from D,L-poly(lactic acid) implanted adjacent to cortical allografts in dogs," <i>J. Orthopaedic Res.</i> 12: 571 (1994).	

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			Complete If Known	
			Application Number	10/665,783
			Filing Date	September 19, 2003
			First Named Inventor	Edward J. Kaplan
			Group Art Unit	
			Examiner Name	
Sheet	11	of	13	Attorney Docket Number
KAP 100 CIP				

## OTHER ART - NON PATENT LITERATURE DOCUMENTS

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		"SUNDBACK, et al., "Manufacture of porous polymer nerve conduits by a novel low-pressure injection molding process," <i>Biomaterials</i> 24: 819-830 (2003).	
		TAMARGO, et al., "Growth inhibition of the 9L glioma using polymers to release heparin and cortisone acetate," <i>J. Neurooncol.</i> 9: 131 (1990).	
		TAMARGO, et al., "Interstitial chemotherapy of the 9L gliosarcoma: controlled release polymers for drug delivery in the brain," <i>Cancer Res.</i> 53: 329 (1993).	
		TAMARGO, et al., "Interstitial delivery of dexamethasone in the brain for the reduction of peritumoral edema," <i>J. Neurosurg.</i> 74: 988 (1991).	
		TAPEN, et al., "Reduction of radioactive seed embolization to the lung following prostate brachytherapy," <i>Biomater.</i> 24: 819-830 (2003).	
		THANOO & JAYAKRISHNAN, "Radiopaque hydrogel microspheres," <i>J. Microencapsulation</i> 6: 233 (1989).	
		THANOO, et al., "Tantalum-loaded polyurethane microspheres for particulate embolization: preparation and properties," <i>Biomater.</i> 12: 525 (1991).	
		VALTONEN, et al., "Interstitial chemotherapy with carmustine-loaded polymers for high-grade gliomas: a randomized double-blind study," <i>Neurosurg.</i> 41: 44 (1997).	
		VIROONCHATAPAN, et al., "Preparation and characterization of dextran magnetite-incorporated thermosensitive liposomes: an on-line flow system for quantifying magnetic responsiveness," <i>Pharm. Res.</i> 12: 1176-1183 (1995).	
		WALTER, et al., "Interstitial taxol delivered from a biodegradable polymer implant against experimental malignant glioma," <i>Cancer Res.</i> 54: 2207 (1994).	

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Sheet 12 of 13

Attorney Docket Number KAP 100 CIP

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		"WANG, et al., "A tough biodegradable elastomer," <i>Nature Biotechnol.</i> 20: 602-606 (2002).	
		WANG, et al., "Intratumoral injection of rhenium-188 microspheres into an animal model of hepatoma," <i>J. Nucl. Med.</i> 39: 1752 (1998).	
		WEI, et al., "Cerboplatin-loaded PLGA microspheres for intracerebral implantation: In vivo characterization," <i>Drug Delivery</i> 4: 301 (1997).	
		WEINGART, et al., "Local delivery of dexamethasone in the brain for the reduction of peritumoral edema," <i>Int. J. Cancer</i> 62: 1 (1995).	
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		YANG, et al., "Diagnostic and therapeutic potential of poly(benzyl L-glutamate)," <i>J. Pharm. Sci.</i> 83: 328 (1994).	
		YAPP, et al., "Cisplatin delivery by biodegradable polymer implant is superior to systemic delivery by osmotic pump or i.p. injection in tumor-bearing mice," <i>Anti-Cancer Drugs</i> 9: 791 (1998).	
		YAPP, et al., "The potentiation of the effect of radiation treatment by intratumoral delivery of cisplatin," <i>Int. J. Radiation Oncol. Biol. Phys.</i> 42: 413 (1998).	
		YAPP, et al., "Tumor treatment by sustained intratumoral release of cisplatin: effects of drug alone and combined with radiation," <i>Int. J. Radiation Oncol. Biol. Phys.</i> 39: 497 (1996).	

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Substitute for Form 1449A/PTO		Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <small>(use as many sheets as necessary)</small>		Application Number	10/665,793
		Filing Date	September 19, 2003
		First Named Inventor	Edward J. Kaplan
		Group Art Unit	
		Examiner Name	
		Attorney Docket Number	KAP 100 CIP

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Sheet 1 of 2 Attorney Name: M. Hartley  
Attorney Docket Number: KAP 100 CIP

U.S. PATENT DOCUMENTS

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## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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Sheet 2 of 2

**Complete if Known**

Application Number	10/665,793
Filing Date	September 19, 2003
First Named Inventor	Edward J. Kaplan
Group Art Unit	1616
Examiner Name	M. Hartley
Attorney Docket Number	KAP 100 CIP

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